

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

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UNITED STATES *ex rel.*  
KURT KROENING,

Plaintiffs,

v.

Case No. 12-CV-366

FOREST PHARMACEUTICALS, INC. and  
FOREST LABORATORIES, INC.,

Defendants.

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UNITED STATES' STATEMENT OF INTEREST

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The United States respectfully submits this statement of interest in response to defendants Forest Pharmaceuticals, Inc. and Forest Laboratories, Inc.'s (collectively "Forest") motion to dismiss the relator's amended complaint (Doc. 50) and notice of supplemental authority (Doc. 60). Forest contends that its motion to dismiss is supported by the Seventh Circuit's recent decision in *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015), which concerned claims for education subsidies from the U.S. Department of Education. Forest misreads *Sanford-Brown* as saying that "to plead a cause of action under the [False Claims Act], Relator must allege an *express false certification* of compliance with a federal or state regulation that was a precondition of payment." Doc. 60-1, at 2 (emphasis added). That is incorrect. Nothing in *Sanford-Brown* requires proof of an "express false certification." *Sanford-Brown* held only that False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"), liability did not follow from violations of particular Department of Education requirements because they were conditions of participation, not conditions of payment. *See* 788 F.3d at 711-12. *Sanford-Brown* thus has no

bearing on cases involving conditions of payment, such as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the “AKS”), at issue here.

The Seventh Circuit decision on point is *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008), which held in a similar context that FCA liability attached to claims for services that were tainted by kickbacks and physician referrals. *Id.* at 452. The court in *Rogan* reached that decision without regard to whether the defendant had expressly certified his compliance with prohibitions on kickbacks and physician referrals. *Id.* at 452. Following *Rogan*, the Court should reject Forest’s invitation to impose additional prerequisites to FCA liability.

### **BACKGROUND**

On April 18, 2012, the relator filed this *qui tam* action under seal, alleging that Forest provided kickbacks in the form of meals and payments to physicians ostensibly engaged as speakers in order to incentivize them to prescribe Forest’s pharmaceutical products. Doc. 1. The relator alleges that, through this scheme, Forest caused false and fraudulent payments for the products to be submitted to Medicare and Medicaid. *Id.* On January 31, 2014, the United States informed the district court that it was unable to decide whether to intervene in the suit at that time, that it would continue investigating the matter, and that the complaint should be unsealed. Doc. 23. The relator subsequently filed an amended complaint, Doc. 41, which was served upon Forest.

On March 16, 2015, Forest moved to dismiss the amended complaint. Among other things, Forest disputes the alleged FCA violations for claims submitted before the enactment of the Patient Protection and Affordable Care Act (“PPACA”). Doc. 51, at 15. The PPACA amended the AKS to confirm that “a claim that includes items or services resulting from [an AKS violation] constitutes a false or fraudulent claim for purposes of [the FCA].” Pub. L. No.

111-148 §6420(f), 124 Stat. 119, 759 (codified as 42 U.S.C. § 1320a-7b(g)). Forest argues that, for claims submitted before the PPACA's enactment, the amended complaint fails because it must, but does not, allege a false express certification of compliance with the AKS. Doc. 51, at 15-19. Forest further contends that the Seventh Circuit's recent *Sanford-Brown* decision supports its view. Doc. 60-1.

Although the United States is not currently a party, it is the real party in interest. Moreover, the United States has an interest in the proper construction of the FCA. *United States ex rel. Einstein v City of New York, New York*, 556 U.S. 928, 930 (2009). The FCA, 31 U.S.C. § 3729 *et seq.*, is the United States' primary tool to redress fraud on the government. Therefore, the United States has a strong interest in the development and correct application of the law in this area. Forest's submissions misstate the law regarding FCA liability. The United States therefore respectfully submits this statement of interest to address Forest's arguments in the wake of the *Sanford-Brown* decision. The United States takes no position on other legal issues or the factual sufficiency of relator's case.

## **ARGUMENT**

### **I. Violations of the Anti-Kickback Statute Can Give Rise to FCA Liability Without Proof of an Express False Certification of Compliance**

Forest mistakenly contends that a FCA plaintiff must allege a "false certification" of compliance with a condition of payment in order to state a claim under § 3729(a)(1)(A). Doc. 51, at 15-19. Nothing in the FCA's text requires a "false certification." *See* 31 U.S.C. § 3729(a). Rather, liability under § 3729(a)(1)(A) attaches to one who "knowingly presents, or causes to be presented, a *false or fraudulent claim* for payment or approval." 31 U.S.C. § 3729(a)(1)(A) (emphasis added); *see, e.g., Sanford-Brown*, 788 F.3d at 709 ("A relator must prove the existence of (1) a *false or fraudulent claim*; (2) which was presented for payment, or caused to be

presented for payment, by the defendant; (3) with knowledge the claim was false.”) (emphasis added).

With that formulation, “Congress wrote expansively, meaning ‘to reach all types of fraud, without qualification, that might result in financial loss to the Government.’” *Cook County v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003); *see also United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). More to the point, Congress intended that a claim may be “false or fraudulent” even if there is no false statement on its face. The Senate Report accompanying the 1986 amendments to the FCA reflects that “claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program.” S. Rep. No. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274.

The question here is whether a claim that includes an item or service that resulted from a kickback is “false or fraudulent” within the meaning of § 3729(a)(1)(A). The Seventh Circuit’s decision in *Rogan* answers the question. *Rogan* affirmed a judgment holding a medical provider liable under the FCA for violating the AKS and Stark Amendment (which forbids the payment of claims that arise an improper physician referral). 517 F.3d at 452. The claims at issue were submitted to Medicare and Medicaid, including claims that did not contain “express certification of compliance with applicable statutes.” *See United States v. Rogan*, 459 F. Supp. 2d 692, 724 (N.D. Ill. 2006). Even for claims that contained no express certification of compliance, the Seventh Circuit affirmed liability because the defendant knew “that illegal referrals occurred” and “that kickbacks were paid,” yet “the bills sent to the United States omitted this information.” *Rogan*, 517 F.3d at 452. Thus, *Rogan* upheld a judgment under the FCA where a defendant knowingly violated the Stark Amendment and AKS, even though he made no express false

statements. See *U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 711 n.13 (7th Cir. 2014) (explaining that *Rogan* involved “omissions”).<sup>1</sup>

Although *Rogan* did not discuss implied versus express certification as such, its rationale makes clear that the FCA reaches one who submits a claim for payment knowing that he has not fulfilled a condition of payment. See 517 F.3d at 452. And, although *Rogan* discusses the issue in terms of “materiality,” it makes clear that compliance with the Stark Amendment and AKS is a condition of payment. See *id.* Moreover, other courts have uniformly held that compliance with these laws is a condition of payment. See, e.g., *U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 393-94 (1st Cir. 2011) (holding that Medicare Provider Agreement and Hospital Cost Reports “make[] it abundantly clear that AKS compliance is a precondition of Medicare payment”); *U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (“Compliance with the AKS is clearly a condition of payment . . . .”); *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) (“Legion other cases have held violations of AKS . . . can be pursued under the FCA, since they would influence the Government’s decision of whether to reimburse Medicaid claims.”); *U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003) (“Compliance with the AKS is thus central to the reimbursement plan of Medicare.”).

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<sup>1</sup> Forest tries to distinguish *Rogan* as involving “express certifications” because certain claims at issue did contain express certifications and the district court stated that FCA liability may rest upon “[f]alsely certifying compliance with the [AKS].” Doc. 57 at 6 n.9 (quoting *United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006)). But, as noted above, other claims did not contain express certifications, and the district court stated that express certification is not necessary: “Even in the absence of an express certification of compliance, the knowing submission of claims by a person who has violated a statute or regulation that contains, on its face, a direct nexus to the government’s payment decision is *also* actionable under the FCA.” *Rogan*, 459 F. Supp. 2d at 717-18 (emphasis added). More importantly, the Seventh Circuit approved the judgment without hinting that FCA liability requires an express certification. See *Rogan*, 517 F.3d at 452.

The PPACA amendments to the AKS simply confirmed what decisions like *Rogan* had already held, that claims for services or items that resulted from kickbacks are “false and fraudulent.” *See* 42 U.S.C. § 1320a-7b(g). As the relator explains, the legislative history to the PPACA amendments to the AKS show Congress understood the amendment to clarify, not change, the law. *See* Relator’s Opp. to Motion to Dismiss, Doc. 56, at 16-17. Thus, it is equally true for claims submitted before and after the PPACA’s enactment that knowingly submitting a claim tainted by kickbacks is “false or fraudulent” for purposes of 31 U.S.C. § 3729(a)(1)(A).

## **II. *Sanford-Brown* Does Not Require an Express False Certification of Compliance**

Contrary to Forest’s argument, *Sanford-Brown* has no bearing on this case. In *Sanford-Brown*, the defendant was a for-profit college that had entered a Program Participation Agreement (“PPA”) with the Department of Education to receive federal education subsidies under Title IV of the Higher Education Act. 788 F.3d at 701. The PPA conditioned the college’s eligibility to participate in the program upon compliance with various statutory, regulatory, and contractual requirements (the “Title IV restrictions”). *Id.* The relator alleged that after entering the PPA, the college violated Title IV restrictions. *Id.* at 701-02. The relator (and the government) “argued that compliance with the PPA is not merely a condition of participation, but a condition of payment.” *Id.* at 710. The relator alleged that by submitting claims for subsidies while knowing it was violating conditions of payment, the college had submitted false and fraudulent claims in violation of § 3729(a)(1)(A).<sup>2</sup> *Id.* at 710-11.

The *Sanford-Brown* court disagreed, holding that the Title IV restrictions were conditions of participation and not conditions of payment. *Id.* at 710-12. It held that “[g]ood-faith entry into the PPA is the condition of payment necessary to be eligible for subsidies under the U.S.

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<sup>2</sup> *Sanford-Brown* also rejected relator’s theory that the college was liable under § 3729(a)(1)(B) for using a false statement—namely, the PPA—in support of its claims. 788 F.3d at 708-09. That holding is not implicated here.

Department of Education’s subsidies program.” *Id.* at 710. The court reasoned that it would be “unreasonable” to “hold that an institution’s continued compliance with thousands of pages of federal statutes and regulations incorporated by reference into the PPA are conditions of payment for purposes of liability under the FCA.” *Id.* at 711. The court therefore “h[eld] that FCA liability is not triggered by an institution’s failure to comply with the Title IV restrictions subsequent to its entry into a PPA, unless the relator proves that the institution’s application to establish initial Title IV eligibility was fraudulent.” *Id.* at 711.<sup>3</sup>

It was in reaching that holding that the *Sanford-Brown* court addressed the “so-called doctrine of implied false certification.” *Id.* at 711-12. Although the court’s discussion is brief, it described the doctrine as imposing FCA liability for “violations of conditions of participation contained in—or incorporated by reference into—a PPA.” *Id.* at 712. The court of appeals rejected that form of implied false certification, holding that a claim submitted in violation of a condition of participation does not necessarily give rise to FCA liability. *Id.* *Sanford-Brown* did not address, let alone reject, the principle that a claim submitted in violation of a condition of payment, such as the AKS, violates the FCA.<sup>4</sup> *Rogan* affirmed that principle and remains the governing law of this circuit.

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<sup>3</sup> *Sanford-Brown*’s holding that the Title IV restrictions are not conditions of payment conflicts with the decision of the only other court of appeals to address the issue, *United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166 (9th Cir. 2006), and the decisions of numerous district courts, *see, e.g., United States ex rel. Sobek v. Educ. Mgmt, LLC*, 2013 WL 2404082, at \*3 (W.D. Pa. 2013).

<sup>4</sup> *Sanford-Brown* purports to “join the Fifth Circuit” in rejecting “this so-called doctrine of implied false certification.” 788 F.3d at 711-12 (citing *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F. 3d 262 (5th Cir. 2010)). In fact, however, the cited Fifth Circuit decision expressly declined to decide the issue. *See Cardinal Health*, 625 F. 3d at 268 (noting that the “Court has not yet recognized the implied-certification theory” and “need not resolve the issue today”).

## **CONCLUSION**

For the foregoing reasons, the Court should reject Forest's argument that a plaintiff must prove the existence of an "express false certification" in order to establish liability under 31 U.S.C. § 3729(a)(1)(A).

Dated this 31th day of August, 2015.

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